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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,889	08/23/1999	LILI FENG	TSRI540.1	3717

7590 06/06/2005

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/194,889	FENG ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,7,18,20-24 and 26-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6-7, 18, 20-24 and 26-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment of claim 1 has been made of record.

Claims 1-3, 6-7, 18, 20-24 and 26-31 are pending and under examination.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Response to Applicants Remarks:

Claim Rejections - 35 USC § 102(e)

Applicant's arguments, see Remarks, filed 11/12/2004, with respect to the rejection(s)of claim(s) 1-3 and 6-7 under 35 USC § 102(e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment of claim 1.

Applicant is reminded that if amendment to claim 1 is made in such a way that new matter is removed then rejection to claims 1-3 and 6-7 under 35 USC § 102(e) would reinstate.

The rejection of claims 18, 20-24, and 26-31 is maintained for the reasons as set forth in the previous office actions.

New Ground of Rejection-

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-7are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for conferring resistance to endotoxic shock in an animal need of resistance to endotoxic shock, comprising administering to the animal a composition having a physiologically effective amount of at least one OB-R agonist ligand. The further dependent claims are drawn to the method where endotoxic shock occurs in sepsis or in systemic inflammatory response. Thus the claims are drawn to an animal that is in need of resistance to endotoxic shock, which has not been disclosed in specification. There is no disclosure when an animal will need resistance to endotoxic shock and also how long (duration of) resistance to endotoxic shock is needed.

This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, . 1 "Written

Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that □applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the □written description inquiry, is *whatever is now claimed* (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Applicant's remarks on page 6, line 2 says that the support for the amendments can be found "in claim 1 as originally filed". However, claim 1 filed on 2/4/1998 does not support the instant claim because it recites "A method for treating a patient having a condition in which regulating energy metabolism during a systemic inflammatory response is desired, comprising administering a composition having a physiologically effective amount of at least one OB-R agonist ligand". The instant specification does not disclose any support for the claimed invention.

Claims 1-3 and 6-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while ~~were it~~enabling for administering LPS to an animal to induce

endotoxic shock and administering an OB-R agonist (OB protein), does not reasonably provide enablement for an animal in need of endotoxic shock. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986).

Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The Nature of the Invention: The claimed invention is drawn to a method for conferring resistance to endotoxic shock in an animal need of resistance to endotoxic shock, comprising administering to the animal a composition having a physiologically effective amount of at least one OB-R agonist ligand.

The state of the prior art and the predictability or lack thereof in the art:

As the claims encompass conferring resistance to endotoxic shock in an animal in need of resistance to endotoxic shock. Grunfeld et al (IDS, J. Clin. Inv. 97:2152-2157, 1996) teach that cytokine administration mimics the metabolic changes of infection (pg. 2152, right column). Administration of gram-negative endotoxin lipopolysaccharide (LPS) creates physiological symptoms of an endotoxic shock in an animal model. But identifying an animal or a patient population in need of conferring resistance to endotoxic shock is highly unpredictable. Because once a bacterial infection has occurred or cytokine levels are high in animal, still does not make an animal in need of resistance to endotoxic shock. The development of an endotoxic shock after an infection or level of cytokine expression would depend on a number of factors such as severity of infection, duration of infection or level of cytokines in system.

A large number of experimentation would be required, if possible, to define an animal in need of resistance for endotoxic shock.

The amount of direction or guidance present and the presence or absence of working examples: Applicants disclose in Example 4 (page 22) where they treated a LPS induced endotoxic shock using OB protein. However, creating a symptom of endotoxic shock does not define an animal in need of resistance to endotoxic shock and when one needs this resistance. After this need is identified then one still need to identify time of administration and duration of treatment to infer resistance for endotoxic shock. This would require huge experimentation and clinical trial to evaluate its validity. There is no working example suggesting that one can identify an animal for resistance to endotoxic shock.

The breadth of the claims and the quantity of experimentation needed: Because the claims encompass a method for conferring resistance to endotoxic shock in an animal need of resistance to endotoxic shock, the lack of direction/guidance presented in the specification regarding conferring resistance to endotoxic shock, the absence of working examples directed to same, the complex nature of invention, and the state of prior art which establishes unpredictability of an animal in need of resistance to endotoxic shock, undue experimentation would be required of the skilled artisan to be able to practice the invention in its full scope.

Rejections which are maintained

Claims 18, 20-24 and 27 stand rejected under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record in the previous office actions.

Claims 18, 20-24, 26, 28-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Grunfeld et al. (J. Clin. Invest. 97: 2152-2157, 1996) for the reasons of record in the previous office actions.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
20 May 2005

JANET ANDRES
PRIMARY EXAMINER